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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,675	01/29/2001	Edward L. Squires	XY-EQUINE3-U	3456

7590 12/18/2002
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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/744,675		SQUIRES ET AL.	
	Examiner		Art Unit	
	Carla Myers		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-69 is/are pending in the application.
- 4a) Of the above claim(s) 15-44, 52-59 and 61-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-51 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3, 4</u> | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's election with traverse of Group IV, claims 45-51 and 60, in Paper No. 10 is acknowledged. Applicants traversed this rejection by arguing that the claims 52-58 should be joined with group IV because it is not unduly burdensome to perform a search of both of these inventions. It is argued that claims 52-58 depend from claim 45 and that the office has in the past examined claims together that include methods of selecting sperm cells and inseminating female mammals. However, as written claims 52-58 do not properly depend from claim 45. There is no specific requirement in claims 52-58 as written to perform each of the method steps set forth in claim 45. Rather, claims 45-51 and 60 are drawn to a method of sorting equine sperm and claims 52-58 are drawn to a distinct method of producing an equid involving sorted equine sperm using at least some sorted equine sperm cells. Furthermore, the methods of claims 45-51 and 60 are distinct from the methods of claims 52-58 in that claims 45-51 and 60 are drawn to methods for sorting sperm cells whereas claims 52-58 are drawn to methods for producing an equid.

2. In the information disclosure statement filed January 29, 2001, the references on pages 7-8 citing pending U.S. applications have been crossed off because copending U.S. applications are not appropriately listed in information disclosure statements. However, these copending applications have been considered by the Examiner. Additionally, in the information disclosure statement filed February 15, 2001, the non-English reference of Linge et al has not been considered fails to include a concise statement of the relevance of the following non-English language reference listed, as required under 37 CFR § 1.98(a)(3): DE 3213963. The above item of information has not been considered by the examiner. The other items of information that are

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otherwise in compliance with the provisions of 37 CFR §1.97-1.98 have been considered by the examiner.

3. Claims 45-51 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 45-51 and 60 are indefinite over the recitation of “establishing a cell source which supplies said equine sperm cells to be sorted” because it is unclear as to what is intended to be encompassed by this step. The claims previously require collecting equine sperm cells and staining equine sperm cells. However, the claims do not clarify how these steps are related to or distinct from the step of establishing a cell source and it is unclear as to what constitutes the cell source.

B. Claims 45-51 and 60 are indefinite and confusing because the claims broadly recite a step of “staining” the equine cells and a step of discriminating between equine cells based on their “sex characteristics.” However, the claims do not clearly set forth the relationship between staining the sperm cells and sorting the sperm cells. It is unclear as to whether the staining of the cells is related to the step of sorting the cells and it is unclear as to how the step of staining the equine sperm cells relates to the remainder of the claim.

C. Claims 45-51 and 60 are further indefinite over the recitation of “having the desired sex characteristics” because this phrase lacks proper antecedent basis and the claims do not clearly set forth what is intended to be encompassed by the desired sex characteristics.

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D. Claims 49-51 and 60 are indefinite over the recitation of “high speed flow cytometry” and “high speed cell sorter” because it is unclear as to what is intended to be encompassed by “high speed”. While it is noted that the specification at page 19 discusses high speed flow cytometry, no clear and precise definition for this phrase is provided in the specification. The specification states that “high speed” is a relative term and that the aspect of what is considered to be high may be varied or may remain absolute. Accordingly, it is unclear as to whether “high speed” is intended to refer to any currently available speed of flow cytometry (i.e. any speed currently employed in the art for the effective separation of sperm cells) or if this phrase is intended to refer to some particular, unstated speed of flow cytometry. It is pointed out that the definition for “high speed” provided in the specification is one which is intended to vary over time. Accordingly, this definition is not considered to be a fixed and precise definition and such a definition does not allow the skilled artisan to determine the meets and bounds of the claimed invention.

E. Claim 60 is indefinite and vague over the recitation of “**accomplished through the use of a method** as described in any of claims 45, 48 or 50.” It is unclear as to what method steps are intended to be included in the method of claim 60 and it is unclear as to how the method of claim 60 is intended to be distinct from the methods of claims 45, 48 and 50.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-47, 49-51 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (U.S. Patent No. 5,985,216) in view of Wilhelm (Cryobiology (1996) 33:320-329).

Rens teaches a method of high speed flow cytometry for sorting sperm. In the method of Rens (see columns 4-6), a sample of sperm is obtained from a male mammal, the sperm is stained with Hoeschst 33342 dye in order to distinguish between viable and nonviable sperm (column 5, lines 4-10), the sperm are sorted in a high speed flow cytometer using a nozzle that forms a stable droplet containing each individual sperm cell (column 2, lines 23-32), the sperm are sorted according to their sex characteristics and isolated populations of X- and Y-chromosome bearing sperm are collected. Approximately 50% of the sperm were viable and the sorting was performed at sampling rates of 500 sperm/sec and 2000 sperm/sec (see column 6). Further, the nozzle allowed for sample rates up to at least 15,000 sperm/sec (column 4, lines 29-31). Rens exemplifies using the claimed sorting method using rabbit, bull, mouse and human sperm (columns 4-7) and states that the sorting method can be used with any mammalian sperm

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(column 4, lines 38-42). Rens does not specifically exemplify applying the sorting method to equine sperm.

However, Wilhelm teaches the use of equine sperm for the purpose of artificial insemination. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rens to the sorting of equine sperm in order to have provided an effective means for distinguishing between and collecting populations of X- and Y-chromosome bearing sperm useful for artificially inseminating equine.

Secondly, Rens does not specify the solution into which the sperm cells are collected. However, Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens so as to have collected the equine sperm in the SMEY solution of skim milk and egg yolk in order to have provided an medium that could be used for freezing and then thawing the sorted equine sperm, thereby providing sorted equine sperm that could be used more effectively for artificially inseminating female equine. With respect to claim 47, the specification has not established any unexpected results with using 4% egg yolk and the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk.

Furthermore, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have

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provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claim 51, Rens does not specify the pressure used to operate the high speed cell sorter. However, methods for sorting equine sperm using high speed cell sorters were well known in the art at the time the invention was made. To determine the optimum conditions for performing a method step is well within the skill of the art. As discussed in MPEP 2144.05(b), “(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

5. Claims 48 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Wilhelm and further in view of Catt (cited in the IDS of January 29, 2001).

The teachings of Rens and Wilhelm are presented above. The combined references do not teach establishing a sheath fluid which contains a HEPES buffered medium. Catt teaches that semen may be diluted in a HEPES-buffered SOF (synthetic oviduct fluid) medium and that such a fluid is suitable for maintaining the viability of spermatozoa (see, e.g., page 252 and 257). Catt also teaches that it is beneficial to sort into a medium containing a cushioning of seminal plasma to increase the viability and motility of sperm. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens in view of Wilhelm so as to have used a HEPES-buffered medium for establishing a sheath fluid because Catt teaches that this is a suitable dilution medium for sperm

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and thereby using HEPES-buffered medium as the sheath fluid would have achieved the benefit of ensuring the viability and motility of the sperm.

7 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Braun (Cyrobiology (1995) 32: 487-492) discusses the effects of different extenders on the motility and plasma membrane integrity of frozen-thawed stallion sperm. Braun teaches that no differences were observed when using skim milk containing 10% egg yolk versus skim milk containing 20% egg yolk (see page 491).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
December 12, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER